

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,064	10/31/2001	Carolyn Elizabeth Lister	01288.0016	4565

7590 04/20/2004

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 February 2004 has been entered.
2. Applicant has amended claims 1-12, and canceled claims 13 and 15. Claims 1-12 and 14 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The objection to Applicant's specification is withdrawn. The Office acknowledges receipt of Applicant's amendment giving status (pending, allowed, etc.) information of all parent priority applications.

Information Disclosure Statement

6. Applicant's IDS, received 10 February 2004, is acknowledged and a signed copy returned herewith.

Claim Rejections - 35 USC § 112, second paragraph

7. Claim 10 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

In claim 10, "gene" remains rejected. Suggested language is "in which the herbicide resistance DNA encodes *bar* resistance or *glyphosate* resistance".

Claim Rejections - 35 USC § 112, first paragraph

8. Claim 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Office acknowledges a typographical mistake in the 12 August 2003 Office Action whereby Applicant's invention is described as "a method of transforming an Allium genus plant...wherein the transformation is carried out with passage through the callus phase..." Applicant's claimed invention, with the exception of claims 7, is drawn to a method of transforming carried out without passage through a callus phase. The Office regrets any inconvenience this may have caused, and thanks Applicant for bringing this to our attention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01) The enablement issues are delivery of DNA by a vector or direct gene transfer, and Agrobacterium mediated transformation of a Allium species plant.

Applicant claims all Allium species plants and transformation with any DNA via any vector or any direct gene transfer.

Guidance in the specification & Predictability of the art. Applicant claims transformation by a vector or direct gene transfer. Applicant teaches transformation by Agrobacterium as described in the specification (page 5, line 11 through page 6, line 14). Agrobacterium and direct gene transfer differ in that direct gene transfer is a mechanical means to deliver DNA and Agrobacterium is a biological process and that the mechanism is quite different for the two. See Hansen et. al., Recent advances in the transformation of plants, Trends in Plant Science, volume 4, No 6, June 1999, pages 226-231, see pages 228, 229 and 230. Agrobacterium-mediated transformation of monocots is particularly unpredictable. Early attempts largely failed, due to failure to identify transformation-competent and regenerable cells (see, e.g., Potrykus, Gene Transfer to Cereals: An Assessment, 1990, Biotechnology, 8(6): 535-542 p. 538, column 2, 3rd full ¶). When success is observed, the transformation appear to be transient only (see, e.g., Narasimhulu et. al., 1996, The Plant Cell, Early transcription of Agrobacterium T-DNA genes in tobacco and maize, vol. 8, p. 874, column 2, top ¶; p. 873, column 2, first full ¶).

Applicant teaches (specification pages 5, lines 11 to page 6, line14), the method outlined below:

- use immature embryos of *Allium cepa* L. ,
- use of *Agrobacterium* LBA4404 bearing the binary vector pBIN-m-gfp-ER or other binary vector, *Agrobacterium* cultures grown to log phase, storage in glycerol at -80°C , overnight *Agrobacterium* cultures treated with $100\text{ }\mu\text{M}$ acetosyringone, cocultivation mix containing $200\text{ }\mu\text{M}$ acetosyringone.
- isolated immature embryos cut into 1mm sections and transferred to 0.8 ml *Agrobacterium* and vortexed for 30 seconds, embryo *Agrobacterium* mix vacuum infiltrated (20 in. Hg) for 30 min before blotting and transferring to solid P5 medium.
- cocultivation for 6 days, after which embryo pieces transferred to selection (geneticin, 10 mg/L ; or basta 5 mg/l) plus trimetin (200).
- embryo pieces cultured in the dark under the same conditions as (Eady, 1998), transferred to fresh medium every 2 weeks. After 3-4 transfers, material transferred to P5 medium + 25 mg/l geneticin or 5 mg/l Basta, and further grown for weeks.
- putative transformed plant tissue transferred to regeneration medium (Eady 1988).
- shoot cultures maintained for 12 weeks and developing shoots transferred to medium to induce rooting.

While the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable, and must be recited in the claims*, this includes time duration, temperature and concentrations.

Applicant traverses saying primarily (Response , p 10) that the Office admits that the claimed invention is enabled, citing the language “even if Applicant were enabled, this would be enable only to the extent the”

Applicant's traversal is unpersuasive. Applicant has misunderstood the cited language, which says that “even if” there were enablement of the claimed invention, (which there is not) it would be enabled only for the method as described in the specification (page 5, line 11 through page 6, line 14).

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden. In fact, Applicant 's 1996 publication, see “Declaration”, final ¶, discussed below, argues against enablement of the claimed invention.

9. **The Declaration of Colin Charles Eady** has been thoroughly considered and is unpersuasive. The Declaration discusses the work of Bidney (EP0486234), citing various deficiencies of the Bidney method.

The Declaration also discusses Eady's 1996 publication, Plant Cell reports (1996) Vol 15, pages 958-962, declaring "that the technique disclosed in the article failed to produce viable transgenic whole plants. I believe that the reason for this was that the particle bombardment, thought for transient expression may have been detrimental to cell survival and that the media used at the time was less than optimal for the recovery of transgenic cells." (Declaration, ¶ 8, pages 4-5).

This argument, discussing Eady's data showing failure to produce viable transgenic whole plants from experiments of particle bombardment of onion immature embryos, supports the Examiner's arguments that the claimed invention is not enabled in scope with the claims (specifically claim 1).

Remarks


10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
April 16, 2004


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